OCT 31 2002

510(k) SUMMARY

K022583

1.	Applicant: Address:	emed, Inc. 191 West Wilbur Road, Suite 103, Thousand Oaks, CA 91350
2.	Contact Persons:	Cornelia Damsky Tel: (203) 323-7535 Kenneth Karasiuk Tel: (805)-446-2200 Ext 14
3.	Preparation Date:	July 29, 2002
4.	Device Submitted:	Flash 1 and accessories
5.	Proprietary Name:	Flash 1
6.	Common Name:	Intense Pulsed Light System
7.	Classification Name:	Laser surgical instrument for use in General and Plastic Surgery and in Dermatology. Product Code GEX, Panel 79
8.	Predicate Device:	The Flash 1 is substantially equivalent to the following currently marketed devices: Palomar's EsteLux, Medical Bio Care's ProLite Pulsed Light Systems, Radiancy's Spa Touch and ESC Medical System's IPL Quantum SR.
9.	Device Description	The Flash 1 Intense Pulsed Light System is a microprocessor controlled system, which uses a Xenon lamp that delivers a wavelength of 590 nanometers. The four principal parts of the system include the capacitor charge system, the electronic control system, the handpiece with lamp box and the control panel.
10.	Intended Use:	The Flash 1 is intended for dematological use by a physician for treatment of vascular and benign pigmented lesions and removal of unwanted hair in all skin types.
11.	Performance Data:	No performance data is required for this Class II device nor requested by the Food and Drug Administration (Office of Device Evaluation). A data base search has been performed to evaluate any adverse effects of the device that is currently marketed. No data submitted for section 807.92 6[(b)(1)(2)(3c)].

SUMMARY:

Beginning with the year, 1966, to the present, a database search was completed for adverse safety and effectiveness reported with use of a pulsed light system for hair removal, treatment of vascular and benign pigmented lesions.. The results of the database search are located in Appendix G.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

emed, Inc.
Ms. Cornelia Damsky
191 West Wilbur Road, Suite 103
Thousand Oaks, California 91360

OCT 31 2002

Re: K022583
Trade/Device Name: Flash 1
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: July 29, 2002
Received: August 5, 2002

Dear Ms. Damsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

Flash 1

This product is intended for dermatological use by physicians for the following:

- Removal of unwanted hair in all skin types
- Treatment of vascular and benign pigmented lesions

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022583